## Food and Drug Administration, HHS

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 64 FR 15684, Apr. 1, 1999]

# § 522.810 Embutramide, chloroquine, and lidocaine solution.

- (a) Specifications. Each milliliter (mL) of solution contains 135 milligrams (mg) embutramide; 45 mg chloroquine phosphate, U.S.P.; and 1.9 mg lidocaine, U.S.P.
- (b) Sponsor. See No. 059130 in  $\S 510.600(c)$  of this chapter.
- (c) Conditions of use in dogs—(1) Amount. One mL per 5 pounds of body weight.
  - (2) Indications for use. For euthanasia.
- (3) *Limitations*. Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 36337, June 23, 2005]

#### §522.812 Enrofloxacin.

- (a) Specifications. Each milliliter (mL) of solution contains:
- (1) 22.7 milligrams (mg) enrofloxacin or
- (2) 100 mg enrofloxacin.
- (b) *Sponsor*. See No. 000859 in §510.600(c) of this chapter.
- (c) Related tolerance. See §556.226 of this chapter.
- (d) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.
- (e) Conditions of use—(1) Dogs. Use the product described in paragraph (a)(1) of this section as follows:
- (i) Amount. 2.5 mg per kilogram (/kg) of body weight (1.13 mg per pound) as a single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 10 days.
- (ii) *Indications for use*. For the management of diseases associated with bacteria susceptible to enrofloxacin.
- (2) *Cattle*. Use the product described in paragraph (a)(2) of this section as follows:
- (i) *Amount*. Single-dose therapy: 7.5 to 12.5 mg/kg of body weight by subcutaneous injection. Multiple-day therapy: 2.5 to 5.0 mg/kg of body weight by

- subcutaneous injection. Treatment should be repeated at 24-hour intervals for 3 days. Additional treatments may be given on days 4 and 5 to animals that have shown clinical improvement but not total recovery.
- (ii) Indications for use. For the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni (previously Haemophilus somnus) in beef and non-lactating dairy cattle.
- (iii) Limitations. Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. Use of enrofloxacin in this class of cattle may cause milk residues. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.
- (3) *Swine*. Use the product described in paragraph (a)(2) of this section as follows:
- (i) *Amount*. Administer 7.5 mg/kg of body weight once, by subcutaneous injection behind the ear.
- (ii) Indications for use. For the treatment and control of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, and Streptococcus suis.
- (iii) *Limitations*. Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.

[72 FR 10597, Mar. 9, 2007, as amended by 73 FR 17890, Apr. 2, 2008; 73 FR 21819, Apr. 23, 2008]

#### §522.820 Erythromycin.

- (a) Sponsor. See No. 061623 ir §510.600(c) of this chapter.
- (b) Specifications—(1) Each milliliter (mL) of solution contains 100 milligrams (mg) erythromycin base.
- (2) Each mL of solution contains 200 mg erythromycin base.
- (c) Related tolerances. See §556.230 of this chapter.
- (d) Conditions of use—(1) Dog. Administer product described in paragraph (b)(1) of this section as follows:

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- (i) *Amount*. 3 to 5 mg per pound (/lb) body weight, intramuscularly, two to three times daily, for up to 5 days.
- (ii) Indications for use. For the treatment of bacterial pneumonia, upper respiratory infections (tonsillitis, bronchitis, tracheitis, pharyngitis, pleurisy), endometritis and metritis, and bacterial wound infections caused by Staphylococcus spp., Streptococcus spp., and Corynebacterium spp., sensitive to erythromycin.
- (iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (2) Cats. Administer product described in paragraph (b)(1) of this section as follows:
- (i) *Amount*. 3 to 5 mg/lb body weight, intramuscularly, two to three times daily, for up to 5 days.
- (ii) Indications for use. For the treatment of bacterial pneumonia, upper respiratory infections (rhinitis, bronchitis), secondary infections associated with panleukopenia, and bacterial wound infections caused by Staphylococcus spp. and Streptococcus spp., susceptible to erythromycin.
- (iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (3) Cattle. Administer products described in paragraph (b) of this section as follows:
- (i) *Amount*. 4 mg/lb body weight by deep intramuscular injection once daily for up to 5 days.
- (ii) Indications for use. For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with Pasteurella multocida susceptible to erythromycin.
- (iii) Limitations. Do not use in female dairy cattle over 20 months of age. Do not slaughter treated animals within 6 days of last treatment. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. To avoid excess trim, do not slaughter within 21 days of last injection.

[72 FR 69142, Dec. 7, 2007]

### §522.840 Estradiol.

(a) *Specifications*. Each silicone rubber implant contains 25.7 or 43.9 milligrams (mg) estradiol and is coated with

- not less than  $0.5\ \mathrm{mg}$  oxytetracycline powder.
- (b) Sponsor. See No. 021641 in \$510.600(c) of this chapter.
- (c)  $Related\ tolerances.$  See §556.240 of this chapter.
- (d) Conditions of use. For implantation in steers and heifers as follows:
- (1) Amount. Insert one 25.7-mg implant every 200 days; insert one 43.9-mg implant every 400 days.
- (2) Indications for use. For increased rate of weight gain in suckling and pastured growing steers; for improved feed efficiency and increased rate of weight gain in confined steers and heifers. No additional effectiveness may be expected from reimplanting in less than 200 days for the 25.7-mg implant or 400 days for the 43.9-mg implant.
- (3) Limitations. For subcutaneous ear implantation in steers and heifers only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[69 FR 67818, Nov. 22, 2004]

# § 522.842 Estradiol benzoate and testosterone propionate.

- (a) *Sponsors*. See sponsors in §510.600(c) of this chapter for use as in paragraph (c) of this section.
- (1) No. 000856 for use as in paragraph (c)(1)(i), (c)(2), and (c)(3) of this section.
- (2) No. 021641 for use as in paragraph (c) of this section.
- (b) Related tolerances. See §§ 556.240 and 556.710 of this chapter.
- (c) Conditions of use. For implantation in heifers as follows:
- (1) Amount. (i) 20 milligrams (mg) estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 8 pellets, each pellet containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate) per implant dose.
- (ii) 20 mg estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 9 pellets, each of 8 pellets containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.